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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------------|------------------|
| 09/873,403 | 06/04/2001 | Pramod K. Srivastava | 8449-178-999 | 1802 |
| 20583 | 7590 | 04/17/2007 | | |
| JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017 | | | EXAMINER YAEN, CHRISTOPHER H | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1643 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 04/17/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--|--|--|
| Office Action Summary | Application No. 09/873,403 | Applicant(s) SRIVASTAVA ET AL. | |
| | Examiner Christopher H. Yaen | Art Unit 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-9,40 and 42-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43-49 and 58-60 is/are allowed.
- 6) ☒ Claim(s) 1,7-9,40,42,50-57 and 61-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: SRIVASTAVA ET AL

The amendment filed 3/2/2007 is acknowledged and entered into the record.

Accordingly, claims 2-6, 10-39, and 41 are canceled without prejudice or disclaimer.

Claims 1, 7-9, 40, 42-64 are pending and examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 102

The rejection of claims 1, 7-9, 40, 42, 50-57, and 61-64 under 35 USC § 102(b) as being anticipated by Bizik *et al* (Int. J. Cancer 1986; 37(1):81-88) is maintained for the reasons of record. Applicant's arguments are substantially similar to the arguments previously presented and rebutted (see Final Office action mailed 11/3/2006). Applicant has, however, submitted a declaration by Dr. Kenneth Parker (herein Parker Declaration) under 37 CFR § 1.132 for consideration. The Parker Declaration asserts that the Bizik *et al* reference does not produce purified α 2M complexes as claimed. The Parker declaration reviews the findings of Bizik *et al* and pays specific attention to figure 1 on page 82. It is the opinion of Dr. Parker that those of skill in the art would believe that the method disclosed by Bizik *et al* would not teach purified α 2m products as claimed. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Although an affidavit or declaration which states only conclusions may have some probative value, such an affidavit or declaration may have little weight when considered in light of all the evidence of record in the application. *In re Brandstadter*, 484 F.2d 1395, 179 USPQ 286 (CCPA 1973). Moreover, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

In the instant case, the Parker declaration is simply the opinion of an expert as to the presence or absence of a protein as determined by intensity of a SDS-Page gel. The declaration relies heavily on Dr. Parker's assessment of a single protein band in an SDS-page gel as representative of a single protein and not a complex of proteins. The declaration does not indicate by objective evidence that the single protein band is devoid of any antigenic peptides which have associated with the α 2M during purification. Aside from the visual inspection of figure 1 on page 82 of Bizik *et al*, those so skill in the art in view of Dr. Parker's declaration would not necessarily preclude the presence of a2m-complexes as claimed.

With regard to the definition of the term "purified", the claims nor the specification offer a specific range as to the upper and lower limits of the term purified as set forth in

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the Parker Declaration. Therefore, the claims do not preclude the interpretation of a purified complex as comprising other cellular components as previously argued.

Therefore, the rejection of the claims under 35 USC § 102 as being anticipated is maintained for the reasons of record.

Conclusion

Claims 1,7-9,40,42,50-57,61-64 are rejected.

This is a continuation of applicant's earlier Application No. 09/873403. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

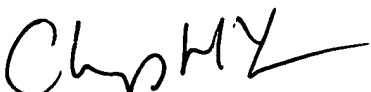
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher Yaen
Art Unit 1643
April 15, 2007


CHRISTOPHER H. YAEN
PRIMARY EXAMINER